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Translated by
Pharmaceuticals and Medical Devices Agency



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of PRECAUTIONS

Acetaminophen (oral dosage form)

October 12, 2023

Therapeutic category

Antipyretics, analgesics and anti-inflammatory agents

Non-proprietary name

Acetaminophen (oral dosage form)

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director-General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
<p>Contraindications (This drug is contraindicated to the following patients.)</p> <p><u>Patients with peptic ulcer [Symptoms may be exacerbated.]</u></p> <p><u>Patients with serious blood abnormalities [Serious outcomes may occur.]</u></p> <p><u>Patients with serious renal disorder [Serious outcomes may occur.]</u></p> <p><u>Patients with serious cardiac function failure [The balance of the cardiovascular system may be compromised, and cardiac failure may be aggravated.]</u></p> <p><u>Patients with aspirin asthma (induction of asthmatic attack due to nonsteroidal anti-inflammatory drug) or a history of the disease [It is considered that the inhibitory activity of prostaglandin synthesis is involved in the onset of aspirin asthma.]</u></p> <p>Precautions for Dosage and Administration (N/A)</p>	<p>Contraindications (This drug is contraindicated to the following patients.)</p> <p>(deleted)</p> <p>(deleted)</p> <p>(deleted)</p> <p>(deleted)</p> <p>(deleted)</p> <p>Precautions for Dosage and Administration</p> <p><u>The maximum dose for patients with aspirin asthma or a history of the disease should be 300 mg or less of acetaminophen per dose.</u></p>

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Careful Administration (Careful administration of this drug is required in the following patients.)

Patients with a history of peptic ulcer [Recurrence of peptic ulcer may be promoted.]

Patients with blood abnormalities or a history of the disease [Blood disorder may occur.]

Patients with renal disorder or a history of the disease [Renal function may worsen.]

Patients with abnormal cardiac function [Symptoms may be exacerbated.]

(N/A)

Careful Administration (Careful administration of this drug is required in the following patients.)

Patients with peptic ulcer or a history of the disease [Symptoms may be exacerbated or recurrence may be promoted.]

Patients with blood abnormalities or a history of the disease [Symptoms may be exacerbated or recurrence may be promoted.]

Patients with renal disorder or a history of the disease [Dose reduction and prolongation of dosing intervals should be considered. Symptoms may be exacerbated or recurrence may be promoted.]

Patients with abnormal cardiac function [Symptoms may be exacerbated or cardiac failure may be aggravated.]

Patients with aspirin asthma (induction of asthmatic attack due to nonsteroidal anti-inflammatory drug) or a history of the disease [It is considered that the inhibitory activity of prostaglandin synthesis is involved in the onset of aspirin asthma, and symptoms may be exacerbated or recurrence may be promoted.]

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.

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Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

Current	Revision
<p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p><u>Patients with peptic ulcer [Symptoms may be exacerbated.]</u></p> <p><u>Patients with serious blood abnormalities [Serious outcomes may occur.]</u></p> <p><u>Patients with serious renal disorder</u></p> <p><u>Patients with serious cardiac function failure [The balance of the cardiovascular system may be compromised, and cardiac failure may be aggravated.]</u></p> <p><u>Patients with aspirin asthma (induction of asthmatic attack due to nonsteroidal anti-inflammatory drug) or a history of the disease [It is considered that the inhibitory activity of prostaglandin synthesis is involved in the onset of aspirin asthma.]</u></p>	<p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p>(deleted)</p> <p>(deleted)</p> <p>(deleted)</p> <p>(deleted)</p> <p>(deleted)</p>
<p>7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION (N/A)</p>	<p>7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p> <p><u>The maximum dose for patients with aspirin asthma or a history of</u></p>

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9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

9.1 Patients with Complication or History of Diseases, etc.

Patients with a history of peptic ulcer
Recurrence of peptic ulcer may be promoted.

Patients with blood abnormalities or a history of the disease
(excluding those with serious blood abnormalities)
Blood disorder may occur.

Patients with abnormal cardiac function (excluding those with serious cardiac function failure)
Symptoms may be exacerbated.

Patients with bronchial asthma (excluding those with aspirin asthma or a history of the disease)
Symptoms may be exacerbated.

(N/A)

the disease should be 300 mg or less of acetaminophen per dose.

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

9.1 Patients with Complication or History of Diseases, etc.

Patients with peptic ulcer or a history of the disease
Symptoms may be exacerbated or recurrence may be promoted.

Patients with blood abnormalities or a history of the disease
Symptoms may be exacerbated or recurrence may be promoted.

Patients with abnormal cardiac function
Symptoms may be exacerbated or cardiac failure may be aggravated.

Patients with bronchial asthma
Symptoms may be exacerbated.

Patients with aspirin asthma (induction of asthmatic attack due to nonsteroidal anti-inflammatory drug) or a history of the disease
It is considered that the inhibitory activity of prostaglandin synthesis is involved in the onset of aspirin asthma, and symptoms may be

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<p>9.2 Patients with renal impairment</p> <p><u>Patients with serious renal impairment</u></p> <p><u>This drug should not be administrated. Serious outcomes may occur.</u></p> <p>Patients with renal disorder or a history of the disease <u>(excluding those with serious renal disorder)</u></p> <p><u>Renal impairment</u> may be exacerbated.</p>	<p><u>exacerbated or recurrence may be promoted.</u></p> <p>9.2 Patients with renal impairment (deleted)</p> <p>Patients with renal disorder or a history of the disease</p> <p><u>Dose reduction and prolongation of dosing intervals should be considered. Symptoms may be exacerbated or recurrence may be promoted.</u></p>
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N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.

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